

REMARKS

I. Status of the Claims

a. General Status of the Claims

Claims 33-60 are pending. Claims 33-41 were previously presented. Claims 42-60 are newly presented. Claims 33 and 37-40 are amended herein. Support for these amendments and the new claims can be found throughout the specification and claims as originally filed.

Regarding the amendment to claim 33. This amendment is made to more precisely define the invention and positively recites the presence of a ternary element by stating that the concentration of one or more ternary elements is greater than 0 to about 10%. While the as filed specification does not explicitly recite one endpoint of this range, namely "greater than 0" this endpoint is readily inferred from the recitation in the specification that the superelastic alloy may contain "up to" a certain amount of ternary element. Accordingly, Applicants submit that no issue of new matter is raised by this amendment.

Regarding the amendment to claims 37-40. These amendments are made to more precisely define the invention. Support for the amendments to claims 37 and 38 can be found throughout the specification as filed, for example, at page 10, lines 6-17. Support for the amendments to claims 39 and 40 is found in the specification and the originally filed claims. Thus, this amendment raises no issue of new matter.

Regarding new claims 42-60. Support for these claims may be found throughout the specification and claims as originally filed. Specifically, support for new claims 42-48, and 51-53 is found at page 18, line 6-page 19 line 2 of the specification as filed. Support for new claims 49 and 50 is found in original claims 9 and 19. Support for new

claims 54 and 55 is found at page 24, lines 10-15 of the specification as filed. Support for new claims 56-60 is found throughout the specification as filed. Accordingly, no issue of new matter is introduced by the addition of new claims 42-60.

Applicants respectfully request entry and prompt consideration of the new and amended claims presented herein.

b. Outstanding Rejections

Claims 33-36 stand rejected under 35 U.S.C. 103(a): 1) as unpatentable over U.S. Patent No. 4,665,906 to Jervis ("Jervis"); and 2) as unpatentable over U.S. Patent No. 5,507,766 to Kugo et al. ("Kugo"). Office Action, pages 2-3. Claims 33-36 further stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over: 1) claims 1-24 of U.S. Patent No. 5,341,818 (the "'818" patent); 2) claims 1-28 of U.S. Patent No. 5,411,476 (the "'476" patent); 3) claims 1-19 of U.S. Patent No. 6,280,539 (the "'539" patent); 4) claims 1-20 of U.S. Patent No. 6,461,453 (the "'453" patent); 5) over claims 1-23 of U.S. Patent No. 6,638,372 (the "'372" patent; and 6) claims 1-35 of U.S. Patent No. 6,682,608 (the "'608" patent). *Id.* at pages 4-5.

Claims 33-37 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,573,520 to Schwartz et al. ("Schwartz"). *Id.* at page 4.

Claims 37-41 stand rejected under the judicially created doctrine of obviousness type double patenting as unpatentable over: 1) claims 1-19 of the '539 patent; 2) claims 1-20 of the '453 patent; 3) claims 1-23 of the '372 patent; and claims 1-35 of the '608 patent. *Id.* at page 5.

Claims 38 and 39 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over the claims 1-19 of U.S. Patent No. 6,419,693 (the "693" patent).

Finally, claims 37, 40, and 41 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over: 1) claims 1-14 of the '693 patent in view of any of claim 1-19 of the '539 patent; 2) claims 1-20 of the '453 patent; 3) claims 1-23 of the '372 patent; or 4) claims 1-25 of the '608 patent.

Applicants respectfully disagree with and traverse each of the outstanding rejections for at least the reasons set forth below.

II. Obviousness Type Double Patenting Rejections

a. Claims 33-36

Claims 33-36 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over: 1) claims 1-24 of U.S. Patent No. 5,341,818; 2) claims 1-28 of U.S. Patent No. 5,411,476; 3) claims 1-19 of U.S. Patent No. 6,280,539; 4) claims 1-20 of U.S. Patent No. 6,461,453; 5) claims 1-23 of U.S. Patent No. 6,638,372; and 6) claims 1-35 of U.S. Patent No. 6,682,608. *Id.* at pages 4-5.

In response, Applicants direct the Examiner's attention to the attached terminal disclaimer. Applicants submit that this terminal disclaimer renders these obviousness type double patenting rejections moot. Accordingly, Applicants respectfully request that these rejections be withdrawn.

b. Claims 37-41

Claims 37-41 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: a) claims 1-19 of U.S. Patent No. 6,280,539; b) claims 1-20 of U.S. Patent No. 6,461,453; c) claims 1-23 of U.S. Patent No. 6,638,372 (the “372” patent); and d) claims 1-35 of U.S. Patent No. 6,682,608 (the “608” patent). *Id.* at page 5.

In response, although Applicants respectfully traverse these rejections, they are rendered moot by the attached terminal disclaimer. Accordingly, Applicants respectfully request that these rejections be withdrawn.

c. Claims 38 and 39

Claims 38 and 39 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,419,693 (“the ‘693 patent”). Applicants respectfully traverse this rejection for at least the following reasons.

According to the Examiner, although the claims of the present application and the ‘693 patent are not identical, they are not patentably distinct because the ‘693 patent claims define a cylindrical intracorporeal device made from a CoCrNiW alloy. Office Action, page 6. In addition, the Examiner argues that it is unclear what distinction, if any, could be made between the materials claimed in the ‘693 patent and those claimed in the present claims.

Applicants submit that there is a clear distinction between present claims 38 and 39 and the claims of the ‘693 patent. Specifically, Applicants submit that the claims of the ‘693 patent are completely silent with respect to an alloy of titanium, nickel, cobalt,

and chromium, wherein the alloy further comprises an element selected from the group consisting of vanadium, palladium, platinum, and niobium, as recited in present claims 38 and 39. In other words, the compositions recited in present claims 38 and 39 are entirely different than the composition of the claims of the '693 patent. Further, the Examiner has provided no evidence or rationale that establishes *why* the claimed invention is considered to be merely an obvious modification of the invention claimed in the '693 patent.

Thus, Applicants submit that the rejection of claims 38 and 39 under the judicially created doctrine of obviousness type double patenting is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

d. Claims 37, 40, and 41

Claims 37, 40, and 41 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over: i) claims 1-14 of U.S. Patent No. 6,419,693 in view of any of claims 1-19 of U.S. Patent No. 6,280,539; ii) claims 1-20 of U.S. Patent No. 6,461,453; iii) claims 1-23 of U.S. Patent No. 6,638,372; or iv) claims 1-25 of U.S. Patent No. 6,682,608. Office Action, page 6.

Regarding items ii-iv above: Applicants respectfully direct the Examiner to the attached terminal disclaimer. This terminal disclaimer is believed to obviate these three rejections. Accordingly, Applicants respectfully request that they be withdrawn.

Regarding item i above: Applicants submit this rejection is improper. Claim 37 recites, *inter alia*, a tubular body comprising a cold worked alloy comprising nickel, titanium, cobalt and chromium. As noted by the Examiner, however, the claims of the '693 patent only disclose an alloy comprising nickel, cobalt, chromium, and tungsten.

Office Action, page 6. Thus, the composition recited in claims 1-14 of the '693 patent is clearly different from the composition recited in present claim 37.

Claims 1-19 of the '539 patent do not cure the deficiencies of the '693 patent, and certainly do not teach the presently claimed invention. The claims of the '539 patent recite a NiTi alloy that may contain one or more additional elements. See claims 1-19 of the '539 patent. This alloy is utilized in an intracorporeal member which has superelastic characteristics, and transforms from an austenite phase to a martensite phase. *Id.*

In view of the above, Applicants submit that the presently claimed invention and the inventions claimed by both the '693 and '539 patents are compositionally different. Further, Applicants submit that the Examiner has not (and indeed cannot) point to any teaching or suggestion in either the '693 patent or the '539 patent that establishes why one of ordinary skill in the art would have found it obvious to modify the invention claimed in the '693 patent per the teachings of the '539 patent.

Thus, Applicants submit that the rejection of claims 37, 40 and 41 under the judicially created doctrine of obviousness type double patenting is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

III. Rejections under 35 U.S.C. §103(a)

a. Rejection of claims 33-36 under 35 U.S.C. §103(a) in view of U.S. Patent No. 4,665,906 to Jarvis

The Examiner has rejected claims 33-36 as unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 4,665,906 ("Jarvis"). Office Action, page 2. According to the Examiner, Jarvis teaches a medical device (e.g., a catheter or cannula) that is made from a NiTi shape memory alloy that transforms to martensite upon the application of

stress and exhibits a recoverable strain of up to 5%. *Id.* The Examiner acknowledges that Jervis does not teach the process steps, transformation stresses, outer wall diameter, and wall thickness recited in the claims. *Id.* However, the Examiner maintains that these deficiencies do not render the claimed invention patentably distinct from Jervis. *Id.* at pages 2, 3. Applicants respectfully traverse this rejection for at least the following reasons.

To establish a prima facie case of obviousness, the Examiner must show, among other things, that the prior art teaches or suggests all of the claim limitations. See M.P.E.P. § 2143. As discussed below, Applicants respectfully submit that the Examiner has failed to meet this burden.

Claim 33 recites, *inter alia*, a tubular body comprising a superelastic NiTi alloy, wherein said alloy further comprises greater than 0 to about 10 atomic % of a ternary element selected from the group consisting of cobalt, chromium, iron and copper. See claim 33 as amended herein. With this in mind, Jervis is completely silent with respect to a superelastic NiTi alloy that further comprises greater than 0 to about 10 atomic % of a ternary element, as presently claimed. Thus, Applicants submit that Jervis does not teach all of the limitations of pending claim 33. Accordingly, Applicants submit that the rejection of claim 33 as unpatentable over Jervis is in error, and respectfully request that it be withdrawn.

With respect to claims 34-36, these claims are allowable over Jervis at least by virtue of their dependence from claim 33.

b. Rejection of claims 33-36 as unpatentable over U.S. Patent No.

5,507,766 to Kugo.

The Examiner has rejected claims 33-36 as unpatentable under 35 U.S.C. §103(a) over Kugo. Office Action, pages 3-4. Although the Examiner admits that Kugo does not teach the claimed processing steps or transformation stress, the Examiner asserts that these features do not render the claimed invention patentably distinct. *Id.* As a result, the Examiner asserts that the burden is on Applicants to show that the claimed invention exhibits some unobvious difference from the product of Kugo. *Id.*

In response, Applicants respectfully direct the Examiner's attention to 35 U.S.C. §102(a), which states, *inter alia*:

"A person shall be entitled to a patent unless: (a) the invention was...described in a printed publication in this or a foreign country, **before** the invention thereof by the applicant for patent..." (emphasis added)

With the above in mind, Applicants note that the present application is a continuation of co-pending U.S. Patent Application Serial No. 10/291,930, filed November 11, 2002, which is a continuation of co-pending U.S. Patent Application Serial No. 10/117,115, filed April 5, 2002, which is a continuation of U.S. Patent Application Serial No. 09/589,592, filed June 7, 2000, which is a continuation of U.S. Patent No. 6,165,292, filed June 7 1995, which is a continuation of U.S. Patent Application Serial No. 08/212,431, filed March 11, 1994, which is a continuation in part of U.S. Patent No. 5,341,818, filed December 22, 1992, and is a continuation in part of U.S. Patent Application Serial No. 07/629,381, filed December 18, 1990. See Specification, page 1, line 1. Applicants submit that the subject matter of claims 33-36

is entirely supported by the disclosure of U.S. Patent No. 5,341,818 ("the '818 patent"). For example, the subject matter of the amended claims 33-36 can be found at column 5, lines 32-33, column 6, lines 62-69, and column 9, lines 10-15 of the '818 patent. Accordingly, claims 33-36 have benefit of a priority date at least as early as December 22, 1992. Moreover, claims 33-36 are supported by the earlier disclosure of the first priority document U.S. Patent Application Serial No. 07/629,381, filed December 18, 1990 as well. (see col. 4 lines 18-61, col. 7 lines 7-42 and col. 10 lines 28-32 of the US Patent 5,411,476 which is a continuation of U.S. Patent Application Serial No. 07/629,381).

In view of the above, Applicants submit that Kugo is not available as prior art with respect to claims 33-36, because it fails to meet the "before" requirement of 35 U.S.C. §102. Accordingly, Applicants respectfully submit that the rejection of claims 33-36 under 35 U.S.C. §103(a) as being unpatentable over Kugo is improper, and respectfully request that it be withdrawn.

c. Rejection of claims 33-37 as unpatentable over U.S. Patent No. 5,573,520 to Schwartz

The Examiner has rejected claims 33-37 under 35 U.S.C. §103(a) as being unpatentable over Schwartz. Office Action, page 4. Applicants respectfully traverse this rejection for at least the following reasons.

As explained above, currently amended claims 33-36 are entitled to the priority date of U.S. Patent Application Serial No. 07/629,381, filed December 18, 1990. Therefore, Schwartz is not available as prior art with respect to claims 33-36, because it fails to meet the "before" requirement of 35 U.S.C. §102. Similarly, currently amended

claim 37 is also entitled to the priority date of December 18, 1990 (see col. 4 lines 40-47 and col. 10 lines 28-32 of the US Patent 5,411,476 which is a continuation of the Patent Application Serial No. 07/629,381, which has a priority date of December 18, 1990).

Therefore, Schwartz is not available as prior art with respect to claim 37 as well, because it fails to meet the "before" requirement of 35 U.S.C. §102. In light of the above, Applicants submit that the rejection of claims 33-37 as unpatentable over Schwartz is improper, and respectfully request that it be withdrawn..

IV. New Claims 42-60

Regarding new claims 42-60, Applicants once again note that the present application is a continuation of co-pending U.S. Patent Application Serial No. 10/291,930, filed November 11, 2002, which is a continuation of co-pending U.S. Patent Application Serial No. 10/117,115, filed April 5, 2002, which is a continuation of U.S. Patent Application Serial No. 09/589,592, filed June 7, 2000, which is a continuation of U.S. Patent No. 6,165,292, filed June 7 1995, which is a continuation of U.S. Patent Application Serial No. 08/212,431, filed March 11, 1994, which is a continuation in part of U.S. Patent No. 5,341,818, filed December 22, 1992, and is a continuation in part of U.S. Patent Application Serial No. 07/629,381, filed December 18, 1990. See Specification, page 1, line 1.

Applicants submit that the subject matter of at least independent claims 43 and 57 is fully supported by the disclosure U.S. Patent Application Serial No. 07/629,381¹.

¹ Applicants once again note that U.S. Patent No. 5,411,476 ("the '476 patent") is a continuation of U.S. Patent Application Serial No. 07/629,381 ("the '381 application"). Accordingly, the specification of the '476 patent and the '381 application are the same.

(continued...)

Thus, these claims have benefit of a priority date at least as early as December 18, 1990.

V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 29, 2005

By: Michele C. Bosch
Michele C. Bosch
Reg. No. 40,524

(...continued)

With this in mind, the subject matter of claims 43 and 57 is disclosed at column 4, lines 40-69 of the '476 patent, of record.